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(54) **Apparatus for the correction of scoliosis.**

(57) Method for correcting the shape of a spinal column. A rod is attached to the vertebrae in the longitudinal direction of the spinal column, at the rear thereof, across the part which is to be corrected. The rod consists of a material, for instance of an Ti-Ni-alloy, with a shape-memory with a transition temperature, lower than the body-temperature. The rod is bent and possibly twisted, corresponding to the curve and/or torsion of the spinal column at a temperature, under the transition-temperature. The rod has a perpendicular cross-section with a linear size in one direction, at least so large, that above the transition-temperature, the rod wants to assume its original shape with a constant force.

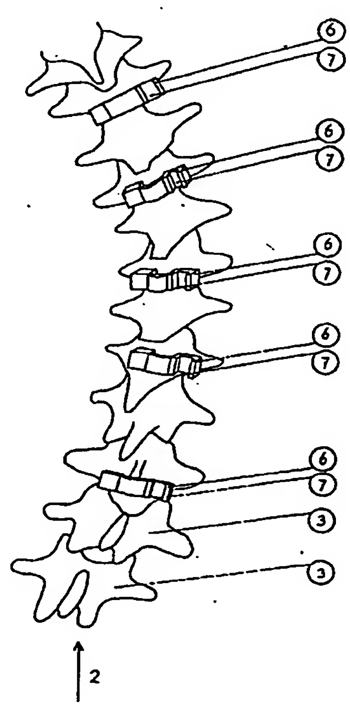

Figure 2

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The invention relates to a method for correcting the shape of a spinal column, whereby a rod is attached to the vertebrae in the longitudinal direction of that spinal column, at the rear thereof, across the part which is to be corrected, which consists of a material with a shape memory, with an appurtaining transition temperature which is lower than the body temperature, which is bent and possibly twisted, corresponding with the curve or, respectively, the torsion of the spinal column, at a temperature which is lower than the transition temperature of the rod.

An important part of orthopaedics is the treatment of patients with a serious shape deformation (scoliosis) of the spinal column and the chest. The shape deformations referred to here are: lateral curvature and axial turning.

Especially if these shape deformations amount to more than 30°, they can lead to a reduction of the lung function and a reduced life expectancy. Light to medium deformations of this type occur in 0.2 to 0.3% of the 16 year olds, and 10 times as much in women than in men.

Lateral curves of 45° (the curves are measured in co-called Cobb angles: the angle between the normals at the ends of the curved part of the spinal column viewed from the rear) or more are qualified as "serious deformations" and are generally treated surgically.

A known, much used surgical method is the so-called Harrington method: hooks are placed under the arches of the vertebrae which mark the end of the curved/deformed part, with which a stainless steel rod is held in place. The part of the rod which is situated between the hooks is then "stretched", so that the hooks and the corresponding end vertebrae are pushed away from each other: - the "curvature" is therefore "decreased". As a result of the visco-elastic qualities of the spinal column this can, after the initial stretching, be stretched further for some time more - for example 10 minutes. The degree to which stretching is possible is determined by the forces which the spinal column can bear without damage arising. After this, bone is taken from the pelvis and laid next to the rod against vertebrae of the spinal columns stretched by the rod. In 3 or 4 months this leads to so-called "fusion" (growing together and thereby stiffening) of the vertebrae concerned. When this "fusion" is a fact the rod is generally removed again.

It turns out that with the aid of this method a reduction of the Cobb angle of approximately 50% can be achieved. As far as the correction of the torsions is concerned this known method has no possibilities.

In the published European patent application no. 84.402149.3 (publication no 0140790) a description is given as to how a deformation of the spinal column can be corrected by attaching a construction to the spinal column, in the longitudinal direction thereof, which contains material with a so-called shape memory. A shape memory means the material, when deformed when it is below a certain temperature - the so- called transition temperature - and is heated to above that temperature, "remembers" it original shape: it wants to assume that "old" shape again and will, if obstructed in doing so, exert a force on the obstructing vicinity. The construction described in the said patent application consists of a bundle of parallel rods with a shape memory. This construction is bent and/or twisted under the transition temperature, so that it assumes the shape of the spinal column at the location which is to be corrected. When heated to above that temperature - i.e.: to body temperature - the construction will want to become "straight" again and will exert a force on the spinal column via the vertebrae to which it is attached. As a result of the visco-elastic qualities of the spinal column it can be corrected - if necessary completely - under the influence of the said force. The desired result is therefore achieved by exposing the spinal column during a longer period of time to a - stretching - force.

In the said patent application a description is given as to how, when using such a construction, the size of the force exerted on the spinal column is dependent on the degree of the deformation. Therefore, as the deformation decreases - during the course of time - the - correcting - force decreases.

In practice it appears that the best results when correcting deformations are reached if the spinal column is not exposed to a force which gradually decreases, but to a constant force. This is especially the case if the deformation is a curvature coupled with a torsion. Surprisingly, it has now turned out that such a constant force can also be achieved by making use of a rod of a material which has a shape memory as is described above - at least, if such a rod has a perpendicular cross-section with a linear size which has at least a particular value. Therefore, if that linear size has that value, or is larger, the force with which the rod wants to assume is original shape when heated to above the transition temperature will be a constant force.

Therefore, according to the invention, relatively "thick" rods must be used. Use is then made of the so-called pseudo-elastic behaviour of metals or metal alloys with a shape memory, above the transition temperature. If necessary they are first heated to above the body temperature and then cooled to that temperature. The attachment to the vertebrae is usually done to alternative vertebrae, therefore per movement segment (vertebra - interver-

tebral disc - vertebra). This because it is often difficult due to lack of space to attach an attachment element to each vertebra. Each spinal column which is to be corrected will set its own specific requirements with regard to the size of the force which can, or respectively must, be applied. The size of that force - and also the temperature above which it occurs - can be set by making a correct choice as concerns the composition and the sizes of the rod which is to be used. Rods of various compositions and sizes therefore need to be available to a surgeon. It has appeared, that Ti-Ni alloys suffice especially well as material with a shape memory for the aims which have been set: preferably in the atomic ratio of about 1:1. The forces which arise are, across a long correction trajectory - for example: 8% stretch - constant to a good degree; the size of the force can be set with the aid of the Ti-Ni ratio. A further advantage of the Ti-Ni alloys is that they are relatively easily shapeable at room temperature or at a lower temperature. A rod thereof can therefore be easily bent and/or twisted in such a manner that it "fits" with the curve of the part of a spinal column which is to be corrected and can be attached to vertebrae of that part.

Experiments have furthermore shown that in particular with linear measurements in the perpendicular cross-section of the rod of about 5 mm, the constant force which is sought can always be achieved. In order to exactly achieve a certain shape of a part of a spinal column, such as the natural S-shape of the spinal column from a lateral view, it is advantageous to pre-program a rod before it is attached to the vertebrae with the aid of attachment elements, for example with the aid of a memory heating. In the case of "the natural S-shape" it is the case, however, that a certain S-shape will arise also without pre-shaping, namely if the effect of the force is small with slight curves of the memory metal. The time necessary for a correction is, even for large deformations of for example 100°, such - three to four weeks - that the correction has been completed when the vertebrae begin to fuse - see with regard to "fusion" the Harrington method mentioned above. May it be noted, that it is, however, improbable that such large angles will still be found at the present time. In general corrections are made before such large deformations arise. A disadvantage of an especially large curve of for example 100° is that the growing together appurtaining thereby is also very serious. Whether the visco-elastic behaviour is also then sufficient for full correction within 4 weeks is the question. The size of the force which arises can be increased by using a rod of a material with a low transition temperature, for example lower than room temperature. The staff is then inserted under-cooled instead of at room temperature.

A large advantage of the method according to the invention is therefore that it can be adjusted entirely to the specific requirements which are laid down in a certain case: by means of a suitable choice of the material composition and the sizes of the rod which is to be used.

The invention also contains the combination of rod and attachment element - a set -, as is applied for the implementation of the said method. Rod and attachment element are adapted to one another and in such a manner that the rod has a cross-section with which it fits in a translation free and rotation free manner into grooves corresponding therewith running in the longitudinal direction of the attachment elements.

A rod with square or rectangular cross-section is preferably chosen with an appurtaining groove in the attachment element. Such a rod is easy to deform with the aid of pliers etc.

In order to prevent the rod moving in the attachment element the latter is equipped with means to anchor the rod therein. For example, attachment is achieved with the aid of a snap lock. Use is also sometimes made of "covers" on top of the groove, in order to thus confine the rod. Or use is also made of screws.

In a preferable design of an attachment element according to the invention this contains an arm which extends approximately perpendicularly to the axial direction of the spinal column around the vertebra and is attached at its other end to the vertebra. The said arm especially fulfills an important function when transferring torsion forces to the vertebrae.

May it be noted, that a small corrective force continues to work on the vertebrae also in the resting position of the rod. When the spinal column has the inclination to curve back again when the rod is present, this force increases. A rod according to the invention can thus be used as an internal corset: it is then no longer necessary to allow the vertebrae to fuse.

The invention will be explained further with the aid of a few figures and with the aid of the drawing.

Experiments have been carried out on spinal columns with lateral curves of 60° to 100° Cobb. The twisting which occurred amounted to between 40° to 45°. Twisting is here taken to mean: the twisting of the most twisted vertebra - approximately the middle vertebra of a deformed part - with regard to a non- twisted - the last - vertebra of a deformed part.

A rod of a Ti-Ni alloy was used, with an atomic ratio of 1:1, with a square cross-section of 5x5 mm. The rod was bent and twisted at room temperature and was attached into the attachment elements with the aid of a pin which was inserted with a pair

of pliers between the rod and the wall of the container. The rod was closed-in in the container with the aid of a cover. It always turned out that within 4 weeks - the time after which the vertebrae start to grow into one another - the final position of the spinal column was reached.

The lateral force was in the order of size of 150 N; 5 Nm was used as a maximum for the moment of torsion.

After being applied the rod was heated to 42 °C, after which it cooled to room temperature. The force which arose did not decrease thereby.

The same kind of experiments have been carried out with a rod of a rectangular cross-section of 4x7 mm. The rod was bent and twisted at room temperature and was anchored in the attachment elements with the aid of a snap lock. The 7 mm side of the cross-section was situated in the mediolateral direction - i.e.: in the plane in which the sideward curve is situated. Also here it appeared that within four weeks - the time needed for vertebra to start to grow together - the utmost position of the spinal column was reached. However, during that four weeks the correction was realised much more gradually and controlled than in the example described hereinbefore, because of the better pseudo-elastic action of the rod as a result of the larger width of the rod. Thus it was possible to realise an increased correction.

In the drawing the figures 1 and 2 are rear views of a spinal column, figure 3 shows a rod according to the invention and figure 4 shows an example of an appurtaining attachment element.

In Fig. 1, 1 shows the lateral curvature of the spinal column 2 - the so-called Cobb angle. The spinal column 2 consists of a piling-up of vertebrae 3. The vertebra 4, situated in approximately the middle of the curved - and therefore to be corrected - part of the spinal column will be twisted to the greatest degree. The twisting is determined by the position of vertebra 4 in comparison with that of the end vertebrae 5 and the part which is to be corrected.

The spinal column 2, shown in Fig. 2, also shows a rear view. It shows how the attachment elements have a groove 7, in which the rod which is to be applied fits. That rod 8 is shown in fig. 3. It is a rod with a square cross-section, consisting of a Ti-Ni alloy. Before it is laid into the groove 7 of the attachment element 6 it is bent and twisted - see the arrows 9 and 10 in Fig. 3 - in accordance with the form of the spinal column 2 which is to be corrected.

Fig. 4 shows an implementation example in detail of an attachment element 6. The groove is shown by 7, in which the rod 8 fits. The element 6 has a - short - arm part 11, which grips around an extension of the vertebra 3 with the aid of a hook 12, thus fixing it.

Claims

1. Method for correcting the shape of a spinal column, whereby a rod is attached to the vertebrae in the longitudinal direction of the spinal column, at the rear thereof, across the part which is to be corrected, which consists of a material with a shape memory, with an appurtaining transition temperature which is lower than the body temperature, which is bent and possibly twisted, corresponding with the curve or, respectively, the torsion of the spinal column, at a temperature which is lower than the transition temperature of the rod,
   characterized in that the rod has a perpendicular cross- section with a linear size in one direction thereof which is at least so large, that above the transition temperature the force with which the rod wants to assume its original shape is a constant force.

2. Method according to claim 1,
   characterized in that the composition and the sizes of the rod and therewith the value of the transition temperature and the size of the force which arises are chosen in such a manner, that they are set to the requirements which are set therefor in a specific case.

3. Method according to claims 1 or 2,
   characterized in that the rod consists of an alloy of Ti and Ni in the atomic ratio of approximately 1:1.

4. Method according to claims 1, 2 or 3,
   characterized in that the linear size in the cross-section of the rod is about 5 mm.

5. Set consisting of one or more rods with appurtaining attachment elements for the implementation of the method according to claims 1, 2, 3 or 4, of which the rods fit in a translation free and rotation free manner into corresponding grooves running in the longitudinal direction of the attachment elements
   characterized in that the rods have rectangular cross- sections, with which they fit into rectangular grooves in the attachment elements.

6. Set consisting of one or more rods with appurtaining attachment elements for the implementation of the method according to claims 1, 2, 3 or 4 and if applicable claim 5,
   characterized in that the attachment elements are equipped with means to fix the attachment of the rod therein.

7. Set according to claim 6, characterized in that a rod is attached in an attachment element with a snap lock.

8. Set according to claim 6, characterized in that the attachment elements are equipped with small covers with which a rod is locked into a groove.

9. Set according to one of the claims 5-8, characterized in that the attachment elements contain arms which extend approximately perpendicularly to the axial direction of the spinal column around the vertebra and are attached to the vertebra at their other end.

10. Rod as referred to in one of the preceding claims.

11. Attachment element, as referred to in one of the preceding claims.

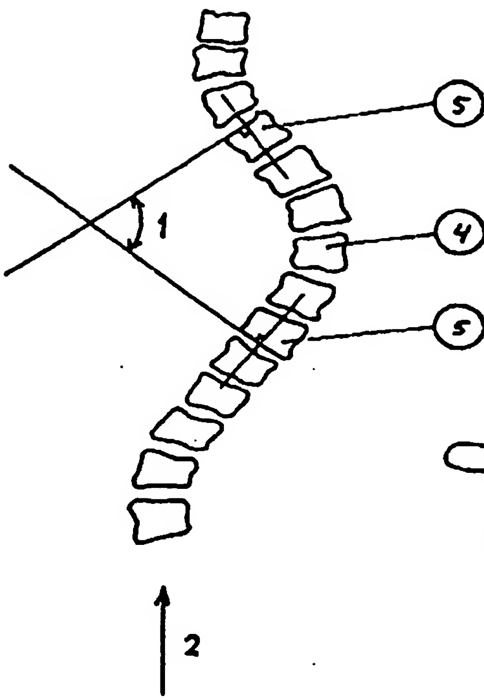

Figure 1

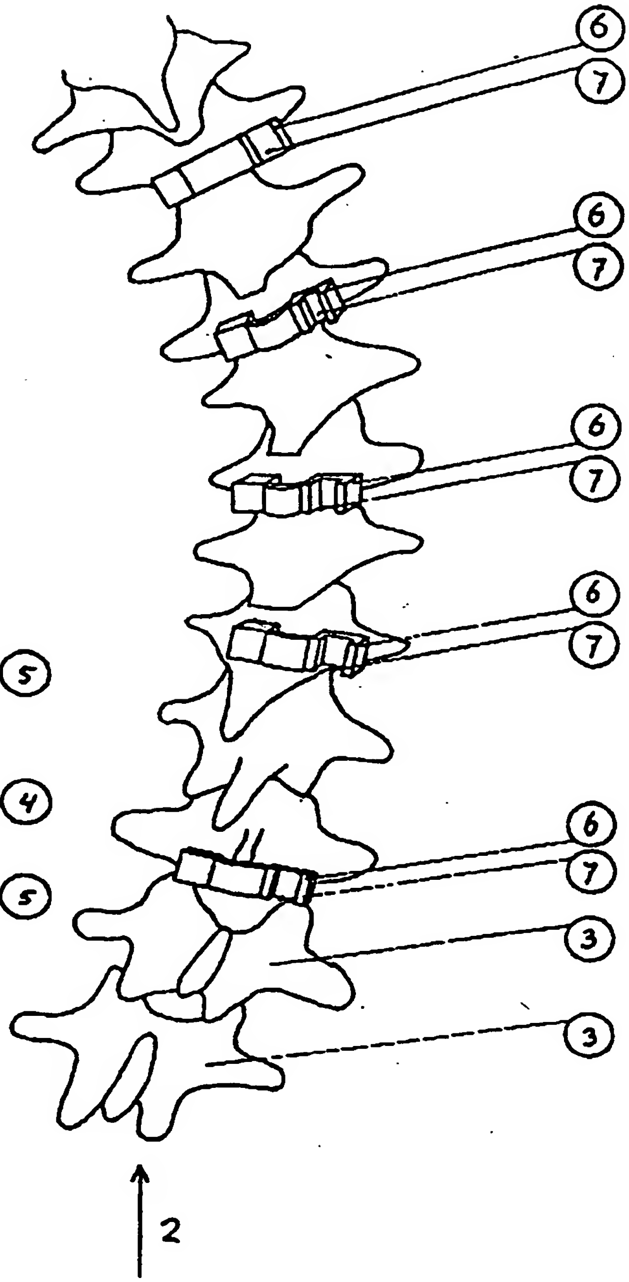

Figure 2

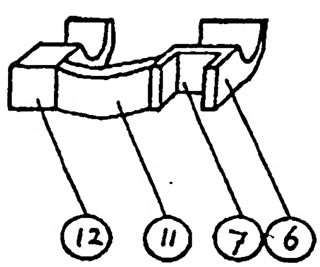

Figure 4

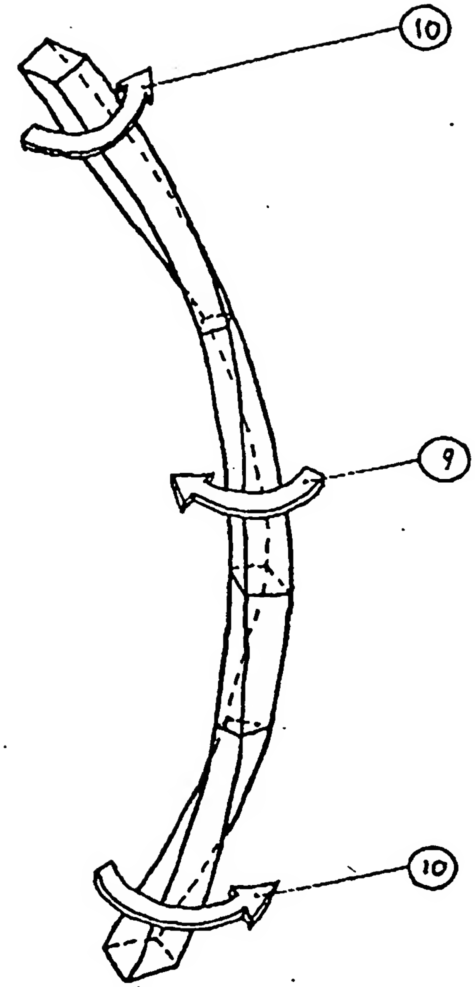

Figure 3

European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application Number

EP 91 20 1948

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
D,X Y	EP-A-0 140 790 (PEZE) * Abstract; figures; page 3, line 17 * ---	5 6,9	A 61 B 17/60
Y	EP-A-0 330 881 (SYNTHES AG) * Column 2, line 28 - column 3, line 40; figures * ---	6	
Y	US-A-4 289 123 (DUNN) * Figures; column 3, line 17 - column 5, line 18 * ---	9	
A	US-A-3 786 806 (JOHNSON) * Claims; column 3, lines 5-8 * ---	5	
A	FR-A-2 624 720 (COTREL) -----		

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 F
A 61 B

INCOMPLETE SEARCH

The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims

Claims searched completely : 5-11

Claims searched incompletely :

Claims not searched : 1-4

Reason for the limitation of the search:

Method for treatment of the human or animal body by surgery or therapy (see article 52(4) of the European Patent Convention).

Place of search	Date of completion of the search	Examiner
THE HAGUE	04-11-1991	STEENBAKKER J.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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A : technological background
O : non-written disclosure
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